Remarks

Claims 1, 2, 4, 5, 9, and 12 to 20 were pending and before the Examiner. By this Amendment, all of the claims have been amended to limit the claims to a tablet or capsule comprising crystalline telmisartan sodium salt with a melting point of T=245°C ± 5°C. As no new matter has been added thereby, entry of the amendments is respectfully requested. Claims 1, 2, 4, 5, 9, and 12 to 20, as amended, are now pending and before the Examiner.

The Examiner also provisionally rejected claims 1, 2, 4, 5, 9, and 12 to 20 for nonstatutory obviousness-type double patenting over claims 8 and 9 of Donsbach *et al.* (U.S. Patent No. 6,737,432) in view of Lacourciere *et al.* (American J. Therapeutics 2002, 9(2), pages 111-7).

In response, applicants undertake to file a terminal disclaimer with respect to Donsbach *et al.*, if (1) the instant claims be found otherwise allowable, and (2) applicants determine that Donsbach *et al.* poses a double patenting issue for the claims pending at that time. Since the scope of the claims may change and moot the rejection, there is no need to address this issue at this time. Accordingly, applicant respectfully requests that the Examiner withdraw the rejection for resolution later.

The Examiner also rejected claims 1, 2, 4, 5, 9, and 12 to 20 as allegedly not enabled and allegedly failing to provide written description under 35 U.S.C. § 112, first paragraph.

In response, applicant has amended the claims and maintains that the amendments render the Examiner's rejections moot. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

The Examiner rejected claims 1, 2, 4, 5, 9, and 12 to 20 as allegedly obvious over Lacourciere *et al.* in view of Donsbach *et al.* (U.S. Patent App. Pub. No. 2003/0130331).

In response, applicant has amended the claims and maintains that such amendments render the Examiner's rejection moot. Lacourciere *et al.* relates to a fixed dose combination of the free acid of telmisartan and hydrochlorothiazide, the composition of which is not disclosed at all. Similarly, Donsbach *et al.* is silent about combinations generally, in particular

combinations of the sodium salt of telmisartan. The disclosure in Donsbach *et al.* of tablets comprising a sodium salt of telmisartan and mannitol does not disclose a pharmaceutically acceptable fixed dose composition comprising a partucular crystalline telmisartan sodium salt and the diuretic hydrochlorothiazide, as presently claimed, much less because the three tablets disclosed in Donsbach *et al.* involve between 0.25 mg and 1 mg of telmisartan sodium salt hemihydrate which is dramatically much less than the effective antihypertensive dosages of 40 mg and 80 mg, see particularly claims 14 to 17. Accordingly, one of skill in the art would not have any reason, much less some motivation or expectation that the result would be successful, to combine the different teachings of Lacourciere *et al.* and Donsbach *et al.* to somehow arrive at the instant claimed invention. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

The Examiner also rejected claims 1, 2, 4, 5, 9, and 12 to 20 as allegedly obvious over Hauel *et al.* (U.S. Patent No. 5,591,762) in view of Dinnebier *et al.* (J. of Pharmaceutical Sci., 2000, Vol. 89 (11), pages 1465-1479), in further view of Vippagunta *et al.* (Adv. Drug Delivery Rev., 2001, Vol. 48).

In response, applicant has amended the claims and maintains that such amendments render the Examiner's rejection moot. For example, the oral suspension of Example 232 of Hauel *et al.* becomes largely irrelevant to the instant claims. Furthermore, Dinnebier *et al.* does not disclose the sodium salt of telmisartan, refering to polymorphic forms of the free acid of telmisartan, but not to any polymorphic forms of the sodium salt of telmisartan, much less that of the instant claimed invention. Vippagunta *et al.* does not mention telmisartan or its sodium salt at all, so its teachings applied to telmisartan is speculative at best. Accordingly, one of skill in the art would not have any reason, much less some motivation or expectation that the result would be successful, to combine the different teachings of Hauel *et al.*, Dinnebier *et al.*, and Vippagunta *et al.* to somehow arrive at the instant claimed invention, which involves a tablet or capsule comprising a crystalline telmisartan sodium salt with a melting point of T=245°C ± 5°C and hydrochlorothiazide, much less the specific narrower dosages of claims of 4, 5, and 12 to 17. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

Applicant submits that all the pending claims are allowable and respectfully solicits a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,

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